

JUN 14 2005

Attorney Ref. No.: 037003 - 0280617

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION OF

Nabil HANNA et al.

Group Art Unit: 1642

Application Serial No. 09/853,581

Examiner: Gary B. Nickol

Filed: May 14, 2001

Title: SYNERGISTIC COMPOSITION AND METHODS FOR TREATING NEOPLASTIC
OR CANCEROUS GROWTHS FOR RESTORING OR BOOSTING HEMATOPOIESIS**STATEMENT PURSUANT TO 37 C.F.R. § 1.132****Mail Stop RCE**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

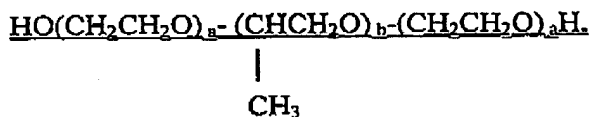
Sir:

Pursuant to section 608.01(v) of the M.P.E.P., the applicants, through their undersigned attorney, hereby state that chemical descriptions of TWEEN 20, TWEEN 40, TWEEN 60, ZWITTERGENT 3-12, TEEPOL HB7, SPAN 85, PEG 1000, and the Pluronic® block polymer L121 (poloxamer 401), which appear in the amended and pending claims 53 and 62 of the present application by the accompanying supplemental amendment were well-known by persons skilled in the art at the time of filing, as evidenced by the following published scientific references:

- (a) Crispens et al., "Evaluation of the anticancer activities of Tweens 20, 40 and 60 in SJL/J mice," *Anticancer Res.*, 1991, 11(1):407-8; the abstract of which describes TWEEN 20 as polyoxyethylenesorbitan monolaurate, TWEEN 40 as polyoxyethylenesorbitan monopalmitate, and TWEEN 60 as polyoxyethylenesorbitan monostearate (abstract attached).
- (b) Miller et al., "The Purification and Characterization of the Cytochrome d Terminal Oxidase Complex of the Escherichia coli Aerobic Respiratory Chain," *J Biol. Chem.*, 1983, 258(15):9159-9165; which describes ZWITTERGENT 3-12 as N-dodecyl-N,N-dimethyl-3-ammonio-1-propanesulfonate (see page 9159, right column at bottom, a copy of which is attached).

30529109v1

- (c) U.S. Patent No. 5,932,212 (Khalaf), filed May 24, 1996; which describes TEEPOL HB7 as alkyl (C9-C13) sodium sulfates in column 10 (copies of the first page and of the page with column 10 are attached).
- (d) Blondino et al., "The quantitative determination of aspirin and its degradation products in a model solution aerosol," J Pharm Biomed Anal., 1995, 13(2):111-9; the abstract of which describes SPAN 85 as sorbitan trioleate (abstract attached).
- (e) Morris et al., "Structural properties of polyethylene glycol-polysorbate 80 mixture, a solid dispersion vehicle," 1992, J Pharm Sci. 81(12):1185-8; the abstract of which describes PEG 1000 as polyethylene glycol having average molecular weight of 1000 (abstract attached).
- (f) Schmolka, "A Review of Block Copolymer Surfactants," J. Am. Oil. Chem. Soc., 1977, 54:110-116 (copy attached), which describes PLURONIC L121 (poloxamer 401) as a block polymer of polyoxyethylene (POE) and polyoxypropylene (POP) subunits having the general structure: $(\text{POE})_a - (\text{POP})_b - (\text{POE})_a$, as shown below:



wherein a and b are such that the average molecular weight of all of the polyoxypropylene (POP) blocks in the molecule is 4000, and approximately 10% of the molecular weight of the copolymer is composed of polyoxyethylene (POE) blocks. See Figure 1 and the paragraph bridging the columns on page 110 of Schmolka, which describes the chemical structure of the poloxamer surfactants, and Table 1 on page 112 of Schmolka, which specifies the characteristics of PLURONIC L121 (poloxamer 401).

- (g) Hunter et al., "The Adjuvant Activity of Nonionic Block Polymer Surfactants," J. Immunol., 1981, 127(3):1244-1250 (copy attached), which states that the block polymer surfactants identified in the specification "are called block polymers because they contain polyoxypropylene (POP) and polyoxyethylene (POE) portions which occur in separate blocks" (see page 1245, top of right column), and describes the chemical structure and characteristics of PLURONIC L121 (poloxamer 401) (see Figure 1 on page 1245).

The applicants, through their undersigned attorney, hereby state that the chemical descriptions of TWEEN 20, TWEEN 40, TWEEN 60, ZWITTERGENT 3-12, TEEPOL HB7, SPAN 85, PEG 1000, and PLURONIC L121 (poloxamer 401), which are added to the specification and pending claims 53 and 62 of the present application by the accompanying

Attorney Ref. No.: 037003 - 0280617

supplemental amendment, are the same as the well-known descriptions of said products given in the above-cited references, and do not constitute new matter.

All statements made of my own knowledge are true and all statements made on information and belief are believed to be true. I acknowledge that willful false statements and the like are punishable by fine, imprisonment, or both under 18 U.S.C. §1001 and may jeopardize the validity of the application or any patent issuing thereon.

Respectfully submitted,



Thomas A. Cawley, Jr., Ph.D.

Reg. No. 40,944

Tel. No. (703) 905-2144 (direct).

Fax No. (703) 905-2500

June 14, 2005
PILLSBURY WINTHROP SHAW PITTMAN LLP
P.O. Box 10500
McLean, VA 22102
(703) 905-2000